

(d) if not, the reasons therefor?

**THE MINISTER OF SCIENCE AND TECHNOLOGY (SHRI KAPIL SIBAL):** (a) and (b) No Sir, there is no single window clearance mechanism available in the Government for approval of genetically engineered products.

(c) and (d) There are standard procedures as per the prevailing Rules-1989 of Environment (Protection) Act, 1986 to cut short the time involved in approving the genetically-engineered products.

**Indian Sub-group on Clinical Research and Transfer of Bio-Materials**

**1300. SHRIMATI N.P. DURGA:** Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) whether Indian Sub-group on Clinical Research and Transfer of Bio-materials under Indo-US Joint Industry Working Group on bio-technology recommended for a new drug authority body on the lines of TRAI and IRDA;

(b) what are the other recommendations made to bring about regulatory and fiscal changes to remove procedural and other impediment in bio-technology sector;

(c) whether it is also a fact that the bio-technology industry is also demanding to treat clinical research expenditure as R&D expenditure; and

(d) if so, the reasons therefor and what benefit would the industry get if it is treated as R&D expenditure?

**THE MINISTER OF SCIENCE AND TECHNOLOGY (SHRI KAPIL SIBAL):** (a) Yes, Sir.

(b) Other recommendations are—

**A. Regulatory**

- 1) A single window clearance mechanism with standard operating procedures (SOPs) for import and export of biologicals; clinical trial and pharmacogenomic samples and export of Special Chemicals, Organisms, Materials, Equipment & Technologies (SCOMET) items.
- 2) Development of policy guidelines for clinical trials.

**B. Fiscal**

- (1) **Income Tax:** Clinical Research Expenditure be treated as R & D Expenditure.
- (2) **Customs:**
  - (i) Allowing import of laboratory consumables by recognized R&D units up to Rs. 1.00 crore.
  - (ii) Removal of anomaly in duty structure between public and private sector.
  - (iii) Permitting unrestricted import for R&D by National Accreditation Board Ltd. (NABL) accredited laboratories.
- (3) **Central Excise:** Exemption of central excise duty for goods that are exempt from customs duty.
- (4) **Service Tax:** Exemption of service tax for Clinical Trial industry.

(c) and (d) Yes, Sir. The reasons advanced for such demand is that clinical research requires substantial R&D inputs and is a critical component of new product development and that such reliefs would make them more competitive and encourage innovation.

**Scientific organizations for research findings**

1301. DR. K. MALAISAMY: Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) the major scientific organizations conducting research and the number of their research findings brought out and how many of them have been put into use;

(b) the parameters and criterion in choosing the research and whether there is any-time frame for completion of the research;

(c) whether there has been a system of monitoring and evaluation of such scientific research; and

(d) whether there has been a facility and possibility for collaborating with much advanced scientific organizations abroad?

THE MINISTER OF SCIENCE AND TECHNOLOGY (SHRI KAPIL SIBAL): (a) to (d) The information is being collected and will be laid on the Table of the House.